

OCT 30 1998

## FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION ANADA 200-147 (Supplement)
- ANADA/GENERIC SPONSOR:**
- Merial Limited  
485 Rt 1 South, Bldg. D-210  
Iselin, NJ 08830
- A. Established Name: **gentamicin** sulfate solution
- B. Trade/Proprietary Name: GENTA-JECT™
- C. Dosage Form: Injectable Solution
- D. How Supplied: GENTAMICIN SULFATE INJECTION  
100 mg/mL is supplied in 100 mL vials.  
Boxes contain twelve vials.
- E. How Dispensed: OTC
- F. Effect of the Supplement:  
addition The supplement provides for the  
of a new species, turkeys, to the  
approved label.
- G. Amount of Active Ingredients: Each mL contains gentarnicin sulfate  
equivalent to 100 mg **gentamicin** base;  
3.2 mg sodium metabisulfite; 0.1 mg  
edetate disodium; 4.5 mg sodium  
acetate anhydrous; 3.0 mg glacial acetic  
acid; 0.8 mg **methylparaben** and 0.1 mg  
propylparaben as preservatives.
- H. Species Chickens, Day-old only,  
Turkeys, One to three day-old

ANADA 200-147

FOIS 1

I. Labeled Dosage and Administration:

Each day-old chicken should be aseptically injected subcutaneously in the neck with a single GENTAMICIN SULFATE INJECTION diluted with sterile, physiologic saline solution to provide 0.2 mg gentamicin in a 0.2 mL dose.

Each 1 to 3 day-old turkey should be aseptically injected subcutaneously in the neck with a single GENTAMICIN SULFATE INJECTION diluted with sterile, physiologic saline solution to provide 1 mg gentarnicin in a 0.2 mL dose.

I. Pharmacological Category:

Antibiotic

J. Indications for Use:

GENTAMICIN SULFATE INJECTION is indicated for use in the prevention of early mortality in day-old chickens caused by *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentarnicin sulfate. Turkeys: as an aid in the prevention of early mortality of 1 to 3 day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.

K. Pioneer/NADA #:

Schering Plough, Garasol®,  
NADA 101-862

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) maybe submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA approval is based on a demonstration that the generic product is bioequivalent to the pioneer product. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA

Policy Letter: 55 FR 24645, June 18, 1990; Bioequivalence Guidance: 61 FR 26182-26186, May 24, 1996).

Based upon the formulation characteristics of the pioneer and generic products, Merial Limited was granted a waiver from conducting an *in vivo* bioequivalence study for GENTAMICIN SULFATE INJECTION when the original ANADA was approved on April 10, 1995. Since that approval, the pioneer sponsor which they copied, Schering Plough, has supplemented their application and added turkeys to their label. Merial Limited is supplementing their generic application to add turkeys to their label.

3. HUMAN FOOD SAFETY:

Withdrawal Time

On January 25, 1994, a waiver from the requirement of an *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product. The original waiver was extended to include turkeys on July 29, 1998. For gentamicin sulfate injectable [21 CFR 522.1044 (a) (d) (3)], do not slaughter chickens for food for at least 5 weeks after treatment. Do not slaughter turkeys for food for at least 9 weeks after treatment.

Regulatory Method:

The analytical method for the determination of gentamicin in tissues uses a microbiological assay procedure. This method is found in the Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols, revised October 1968, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

4. AGENCY CONCLUSION:

This is a supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the act and demonstrates that GENTAMICIN SULFATE INJECTION when used under the proposed use in turkeys, is safe and effective for its labeled indications.

Attachment: Generic labeling

# GENTA-JECT™

(Gentamicin Sulfate injection)  
Sterile Injection Veterinary  
Injection — 100 mg/mL

Anti-Infective for  
Day-Old Chickens and One to Three Day-Old Turkeya

**DESCRIPTION:** Each milliliter of GENTAMICIN SULFATE INJECTION contains gentamicin sulfate veterinary, equivalent to 100 mg gentamicin base; 3.2 mg sodium metabisulfite; 0.1 mg edetate disodium; 4.5 mg sodium acetate anhydrous; 3.0 mg glacial acetic acid; 0.8 mg methylparaben and 0.1 mg propylparaben as preservatives; water for injection q.s.

**CHEMISTRY** Gentamicin sulfate veterinary is a bactericidal aminoglycoside antibiotic derived from *Micromonospora purpurea* of the Actinomycetes group. It is a powder, readily soluble in water and basic in nature. Gentamicin aqueous solutions do not require refrigeration and are stable over a wide range of temperatures and PH.

**INDICATIONS:** GENTAMICIN SULFATE INJECTION is recommended for the prevention of early mortality in day-old chickens associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate. Turkeys - as an aid in the prevention of early mortality of 1 to 3 day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.

**DOSAGE AND ADMINISTRATION:** Chickens - Each day-old chicken should be aseptically injected subcutaneously in the neck with GENTAMICIN SULFATE INJECTION diluted with sterile, physiologic saline solution to provide 0.2 mg gentamicin in a 0.2 mL dose. This concentration can be provided by diluting GENTAMICIN SULFATE INJECTION as follows:



GENTAMICIN SULFATE INJECTION mL	Sterile Saline mL	No. of Doses	Dose/Chicken mL
1	99	500	0.2
2	198	1000	0.2
4	396	2000	0.2
10	990	5000	0.2
100 (1 vial)	9900	50000	0.2

Turkeys - Each 1 to 3 day-old turkey should be aseptically injected subcutaneously in the neck with GENTAMICIN SULFATE INJECTION diluted with sterile, physiologic saline solution to provide 1 mg gentamicin in a 0.2 mL dose. The dose should be injected under the loose skin on the top of the neck, halfway between the head and base of the neck. This concentration can be provided by diluting GENTAMICIN SULFATE INJECTION as follows:

GENTAMICIN SULFATE INJECTION mL	Sterile saline mL	No. of Doses	Dose/Turkey mL
1	19	100	0.2
2	38	200	0.2
4	76	400	0.2
10	190	1000	0.2
100 (1 vial)	1900	10000	0.2

Clean and sterilize needles and syringes by boiling in water for 15 minutes prior to use. Disinfect the injection site and top of the bottle with a suitable disinfectant, such as 70% isopropyl alcohol.

Use all precautions to prevent contamination of vial contents.


**WARNING:** For use in day-old chickens and 1 to 3 day-old turkeys only. Chickens injected with GENTAMICIN SULFATE INJECTION must not be slaughtered for food for at least five (5) weeks following treatment. Turkeys injected with GENTAMICIN SULFATE INJECTION must not be slaughtered for food for at least nine (9) weeks following treatment.
 

## HOW SUPPLIED

GENTAMICIN SULFATE INJECTION 100mg/mL is available in 100 mL vials.

Protect from freezing.

Store between 2°C and 30°C (36°F and 86°F)

ANADA 200-147. Approved by FDA

Distributed by:

**Wade Jones Company**  
Hwy 71 North  
Lowell, AR 72745

1613300083-398



APR 14 1998

0 009

**WARNING:** For use in day-old chickens only. Injected chickens must not be slaughtered for food for at least five (5) weeks following treatment. For use in 1 to 3 day-old turkeys only. Injected turkeys must not be slaughtered for food for at least nine (9) weeks following treatment.

**Distributed By:**  
Wade Jones Company  
Hwy. 71 North  
Lowell, AR 72745

**TAKE** 2ss45  
  
**OBSERVE LABEL Product DIRECTIONS**

**613301**  
1612S0S0S3-2SS



**(Gentamicin Sulfate Injection)**

### Sterile Injection Veterinary

FOR ANIMAL USE ONLY  
NOT FOR HUMAN USE  
KEEP OUT OF REACH OF CHILDREN

**Anti-Infective for Day-Old Chickens  
and 1 to 3 Day-Old Turkeys**  
AMAZIL 990, LAY Approved by FDA

**NET CONTENTS**  
**100 ml (3.4 Fl Oz)**

**For Subcutaneous Use Only**

EACH mL CONTAINS: Gentamicin sulfate (water); 1% w/v; procaine hydrochloride base; 3.2 mg/mL; methylcellulose, 0.1 mg/mL; disodium edetate dihydrate, 0.1 mg/mL; sodium acetate anhydrous, 30 mg/mL; acetic acid, 0.0 mL; methylparaben and 0.1 mg propylparaben, 66 preservatives; water for injection q.s.

**DOSAGE AND ADMINISTRATION:** Inject each day at chicken subcutaneously in the neck with GENTAMICIN SULFATE INJECTION diluted with sterile physiologic saline solution to provide 2 mg gentamicin in 1 cc of dilution daily. Dilute 1 cc of GENTAMICIN SULFATE INJECTION in the neck with GENTAMICIN SULFATE INJECTION diluted with sterile physiologic saline solution to provide 1 mg gentamicin in a 0.2 mL dose.

For additional information please see accompanying insert.

LOT NO.:

**EXPIRES:**

APR 14 1998

0 007

**INDICATIONS:** GENTAMICIN SULFATE INJECTION is recommended for the prevention of early mortality in day-old chickens associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate. Turkeys as an aid in the prevention of early mortality of 1 to 3 day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.

**PROTECT FROM FREEZING.**

**STORE BETWEEN 2°C AND 30°C (36°F AND 86°F).**

**WARNING** For use in day-old chickens only. Injected chickens must not be slaughtered for food for at least five (5) weeks following treatment. For use in 1 to 3 day-old turkeys only. Injected turkeys must not be slaughtered for food for at least nine (9) weeks following treatment.

Distributed By:  
Wade Jones Company  
Hwy. 71 North  
Lowell, AR 72745

**TAKE TIME**  
  
**OBSERVE LABEL Product 613301**  
**DIRECTIONS** 1613304063-396

# GENTA-JECT



**(Gentamicin Sulfate Injection)**

**Sterile Injection Veterinary**

FOR ANIMAL USE ONLY  
NOT FOR HUMAN USE  
KEEP OUT OF REACH OF CHILDREN

Anti-infective for Day-Old Chickens  
and 1 to 3 Day-Old Turkeys  
ANADA 200-147, Approved by FDA

**NET CONTENTS**  
100 ml (3.4 FlOz)

**For Subcutaneous use Only**

**EACH mL CONTAINS:** Gentamicin sulfate veterinary equivalent 100 mg gentamicin base; 3.2 mg sodium metabisulfite, 0.1 mg edetate disodium; 4.5 mg sodium acetate anhydrous; 0 mg glacial acetic acid; 0.8 mg methylparaben and 0.1 mg propylparaben as preservative. iii: water injection q.s.

**DOSAGE AND ADMINISTRATION:** Inject each day old chicken subcutaneously in the neck with GENTAMICIN SULFATE INJECTION diluted with sterile physiologic saline solution to provide 0.2 mg gentamicin in a 0.2 ml dose. Turkeys inject each 1 to 3 day-old turkey subcutaneously in the neck with GENTAMICIN SULFATE INJECTION diluted with sterile physiologic saline solution to provide 1 mg gentamicin in a 0.2 mL dose.

For additional information please see accompanying insert.

LOT NO.:

EXPIRES

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APR 14 1998

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